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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,511	12/22/2000	Douglas G. Clark	VTN-527	1745

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EXAMINER

SCHWARTZ, JORDAN MARC

ART UNIT PAPER NUMBER

2873

DATE MAILED: 03/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/745,511

Applicant(s)

CLARK ET AL.

Examiner

Jordan M. Schwartz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 December 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claim 16 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In reference to claim 16, it is not clear if applicant is claiming that the lens comprises acquafilcon and etafilcon and one of genfilcon or lenefilcon or if applicant is claiming that the lens comprises one of acquafilcon or etafilcon or genfilcon or lenefilcon (the latter being the assumed meaning for purposes of examination) and the lack of clarity renders the claim vague and indefinite.

In reference to claim 31, applicant claims "translucent base layer" which renders the claim vague and indefinite. Specifically, in claim 26, applicant is claiming that the central portion of the base layer is clear and just a zone within it is translucent. Therefore it is not clear if the intended meaning is that the base layer is deposited before any color layers or that the translucent color zone of the base layer is deposited before any other colors and the lack of clarity renders the claim vague and indefinite. For purposes of examination the assumed meaning of claim 31 is "wherein the translucent color zone of the base layer is deposited".

Claim Objections

Claims 3 and 25-26 (and their respective dependent claims) are objected to for the following reasons. Since the intended meaning could be determined from what is set

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forth in the specification and figures, 112 rejections were not made but instead these lack of clarity issues were raised in the following objections.

In reference to claim 3, applicant states that "the base layer and the additional color layer cover greater..." and the assumed meaning is "color zones of the base layer and the additional color layer cover greater..." similar to claim 2.

In reference to claim 25, "second translucent color zone" is assumed to mean "second translucent color layer" similar to claims 1 and 26.

In reference to claim 26, "an opaque color layers" (plural) is assumed to mean "an opaque color layer" (singular).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 15, 17-18, 21-22 and 25-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Rawlings patent no. 5,120,121 (hereinafter referred to as "Rawlings'121).

Rawlings'121 reads on these claims by disclosing the limitations therein including the following: a contact lens (abstract); comprising one surface having a "base layer" (Figure 4, column 9, line 48, the tint mask underlay or overlay being considered as the "base layer"); the base layer having a clear central zone (Figure 4) and a translucent color zone (Figure 4, column 16, line 59 to column 17, line 2 and column 17, line 9).

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Rawlings'121 further discloses one or more additional color layers (Figures 3 and 5, column 15, line 47, column 16, lines 36-62 with the iris patterning portion of Figure 3 considered as the "additional color layer"); the additional color layer as either a second translucent layer or an opaque layer (column 8, line 16); the additional color layer has a clear central zone and a color layer (Figure 3). So, the mask layer can be considered as the "base layer" which is disclosed as having a clear central zone and a translucent color zone and the colored pattern layer can be considered as the "one or more additional color layer" and it is disclosed as being either translucent or opaque and having a clear central zone and a color zone. Rawlings'121 further discloses the color zones covering greater than 85 percent of the area of the iris (figure 5, column 6, line 67 to column 7, line 12); greater than "about 90 percent" (column 6, line 30, column 7, line 5). In reference to claim 4, since Rawlings'121 discloses that the colored portions of Figures 1-2 can have a central clear and a translucent color zone (column 8, line 16) then the Figure 2 layer can be considered as the "base layer" and the mask layer can be considered as the "additional color layer" and Rawlings'121 therefore discloses the layers coverage within the claimed percentages (Figures 2 and 4, column 6, line 67 to column 7, line 12). Rawlings'121 further discloses the base layer of uniform color (column 7, line 46 to column 8, line 59); the base layer comprising shapes of striae (Figure 4) or lines (Figures 1-2 if the colored pattern layer and not the mask layer is considered as the "base layer"); and that multiple layers can be applied to the same surface (column 8, lines 50-59). In reference to claim 15, Rawlings'121 further discloses a clear pre-polymer layer (column 12, lines 5-28) and regardless, since the base layers

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are being applied to a contact lens surface, the contact lens surface will inherently comprise a pre-polymer layer. Rawlings'121 further discloses that the method can comprise depositing onto a molding surface the layers (column 7, line 46 to column 8, line 34 and column 11, line 45 to column 15, line 36) and the deposition by pad printing (column 11, line 51-58).

Claims 1, 11-12, 15, 19-20 and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Knapp patent no. 4,720,188 (hereinafter referred to as "Knapp'188).

Knapp'188 reads on these claims by disclosing the limitations therein including the following: a contact lens (abstract); comprising one surface having a "base layer" (column 2, line 54 to column 3, line 2 i.e. the layer having the pattern of dots); the base layer having a clear central zone (column 3, line 26 in that the dot pattern is deposited on the iris section and therefore the central pupil section is a clear central zone) and a translucent color zone (column 2, line 67 and column 3, line 26 in that the dot pattern is deposited on the iris section and is disclosed as translucent). Knapp'188 further discloses one or more additional color layers (column 4, line 5); the additional color layer as either a second translucent layer or an opaque layer (column 2, line 67); the additional color layer has a clear central zone and a color layer (column 3, line 26 in that the dot pattern is deposited on the iris section and therefore the central pupil section is a clear central zone and column 2, line 67 and column 3, line 26 in that the dot pattern is deposited on the iris section and is disclosed as translucent). So, the first printed pattern can be considered as the "base layer" which is disclosed as having a clear

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central zone and a translucent color zone and the colored pattern layer can be considered as the repeat of the pattern and it is disclosed as being either translucent or opaque and will likewise have a clear central zone and a color zone. Knapp'188 further discloses the layers having a radially gradient density (column 3, lines 9-14); the layers comprising shapes of circles (Figure 2). In reference to claim 15, since the patterns i.e. layers are being applied to a contact lens surface, the contact lens surface will inherently comprise a pre-polymer layer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rawlings'121 or Knapp'188.

Rawlings'121 and Knapp'188 disclose as is set forth above but do not specifically disclose the lens comprising one of aquafilcon, etafilcon, genfilcon or lenefilcon (as this claim is understood). However, the examiner takes Judicial Notice that it is well known in the art of contact lenses for such lenses to comprise one or more of the above materials. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have the contact lens of Rawlings'121 or Knapp'188 as comprising one of aquafilcon, etafilcon, genfilcon or lenefilcon since

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such materials are well known in the art of contact lenses as a material used for making contact lenses.

Claims 11-14, 19-20 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rawlings'121 in view of Knapp'188.

In reference to these claims, Rawlings'121 discloses as is set forth above but discloses the color zones of uniform color and not of radially gradient colors as claimed. Knapp'188 teaches that in colored contact lenses comprising central clear zones and colored zones to simulate the iris that it is desirable to use a radially gradient pattern for the purpose of providing a more natural looking iris (column 3, lines 9-15). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have the color zones of Rawlings'121 of radially gradient colors since Knapp'188 teaches that in colored contact lenses comprising central clear zones and colored zones to simulate the iris that it is desirable to use a radially gradient pattern for the purpose of providing a more natural looking iris.

Prior Art Citations

Su et al patent no. 5,018,849 is being cited herein to show a contact lens that would read on or make obvious a number of the above rejected claims, however, such rejections would have been repetitive. Specifically, the masking section "28" is disclosed as having a clear central area and translucent colored iris section and therefore masking section "28" can be considered as the "base layer". Furthermore, the colored portion of upper surface "26" leaves the central portion of the lens as clear and colors

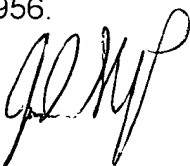
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the iris section and therefore upper surface "26" can be considered as the "additional color layer".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jordan M. Schwartz whose telephone number is (703) 308-1286. The examiner can normally be reached on Monday to Friday (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Georgia Y. Epps can be reached at (703) 308-4883. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7722 for regular communications and (703) 308-7722 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.



Jordan M. Schwartz
Primary Examiner
Art Unit 2873
March 7, 2002